## Congressman C.A. Dutch Ruppersberger Committee on Government Reform

## "RU-486 - Demonstrating a Low Standard for Women's Health?"

May 17, 2006

## Statement:

I look forward to the testimony of our expert witnesses here today. I hope that we will be able to have an honest discussion about women's health.

RU-486 underwent a rigorous four-year review process at the FDA – more rigorous than most drugs. As you know, it was considered under a select set of regulations called "subpart H," which allowed the FDA to add more conditions on the drug's distribution and use.

Since its approval in 2000, nearly 600,000 women in the U.S. have used RU-486. It has proven to be a safe and effective means of terminating <u>early</u> pregnancy.

Because of this medical option, millions of women worldwide, including survivors of sexual assault, have had the right to end an early pregnancy with privacy and dignity.

Tragically, there have been four confirmed deaths in the U.S. from bacterial infection in women who used RU-486. At this point, we <u>do not know what caused these infections</u> or if these deaths are at all related to the use of RU-486.

Fortunately, the CDC and FDA have moved quickly to investigate these incidents.

Earlier this month, 486 scientists from the nation's leading public health agencies gathered in Atlanta to discuss the bacteria that caused these deaths and the risks it poses to pregnant women.

Career scientists and doctors are the best equipped to investigate this issue and I know they will get to the bottom of it.

We must rely on accepted medical standards for determining the safety and efficacy of a medication.

The future of RU-486 should lie with the FDA and the medical community, not with Members of Congress who do not yet have a full picture of the impact of RU-486 on women's health.

Mr. Chairman, I yield back.